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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,135	GUNZBURG ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *9-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/925214* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In paper no. 9, applicant added claims 18-22. Claims 1-22 are pending in the application.

Election/Restrictions

Applicant's election with traverse of group I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that a retroviral system comprises a retroviral vector and a packaging cell line. Applicant points out the subject matter of each claim and notes that a packaging cell line is not required with the vector of claims 5-7. Applicant asserts that claims 5-7 and 18-22 should be included with the invention of group I.

Applicant's arguments have been considered and are found persuasive. Claims 5-7 and 18-22 are rejoined with group I. Claims 9-17 are withdrawn from consideration due to non-elected subject matter. Claims 1-8 and 18-22 are under consideration.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5 and 18 require a peptide with Sag activity or a "derivative of the peptide with Sag activity". It is unclear from this phrase whether the derivative also has Sag activity or not. On page 10, lines 18-26, the specification states that derivatives of the peptide with Sag activity are peptides having the activity of Sag, but differ in amino acid structure. However, this definition does not define the metes and bounds of which structural components are required for Sag activity. This affects dependent claims 2-4, 6-8 and 19-22.

Claim 8 provides for the use of a recombinant vector, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 21 and 22 are drawn to a host cell infected with a retroviral vector or a "derivative thereof". Although the specification discusses different vectors on pages 8-10, it cannot be determined what a derivative of a retroviral vector is. The structural and/or functional characteristics intended to be encompassed by the derivative cannot be determined from the claims or the specification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 18-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-8 and 18-22 require a peptide with Sag activity or a "derivative of the peptide with Sag activity". Claims 21 and 22 additionally recite a host cell infected with a retroviral vector or a "derivative thereof". The claims do not require that the Sag derivatives or the derivative of the retroviral vector possess any particular distinguishing feature, biologic activity, or conserved structure.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, neither the claims nor the specification identify a structural or functional feature of the Sag derivatives or the derivative of the retroviral vector that is required to be conserved from the parent Sag peptide or vector. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of Sag derivatives or the derivative of the retroviral vector.

Therefore, only the Sag peptide and a retroviral vector comprising the 5' and 3' long terminal repeat structures described in claims 5 and 18, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Lapeyre et al. (WO 95/00178).

The claims are drawn to a recombinant vector comprising a nucleotide sequence capable of infecting and directing the expression of a coding sequence and a sequence encoding a peptide

with Sag activity. (Sag activity is defined in the specification as superantigen activity on page 2, lines 9-10.)

Lapeyre et al. claim a DNA comprising a superantigen under the control of a promoter that is capable of expression in a mammalian cell. The DNA is a recombinant vector, a plasmid a viral vector, a retroviral vector or an adeno-associated virus. See claims 1, 14-17 and 20. Therefore, Lapeyre et al. anticipate a recombinant vector comprising a nucleotide sequence capable of infecting and directing the expression of a coding sequence and a sequence encoding a peptide with Sag activity.

To obviate this rejection, it is suggested that applicant amend the claims to specify mouse mammary tumour virus (MMTV) Sag to differentiate it from other superantigens.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunzburg et al. (Nature. 1993; 364 (July 8): 154-158) and Gilboa (US 5,658,775).

See the summary of claims 1-4 above. Claims 5-8 and 18-22 are drawn to a recombinant replication-defective retroviral vector capable of promoter conversion comprising a 5' LTR comprising the structure U3-R-U5, a sequence encoding a peptide with Sag activity and a 3' LTR comprising a completely or partially deleted U3 region that is replaced by a promoter expressing heterologous DNA sequences followed by R-U5. The claims also require a host cell

infected with the retroviral vector. The recombinant vector is used for amplification of B- or T-cells.

Gunzburg et al. identify a promoter located in the U3 region of the 5' MMTV LTR and splice donor/acceptor sites expressing an endogenous superantigen (Sag), see Figure 1a. Gunzburg et al. teach that superantigen expression results in T-cell proliferation, see the abstract and the last paragraph on page 158. Gunzburg et al. do not teach a replication-defective retrovirus comprising a completely or partially deleted U3 region that is replaced by a promoter expressing heterologous DNA sequences followed by R-U5 or a host cell comprising the retroviral construct.

Gilboa teaches a murine retroviral vector comprising a 5' LTR and a completely or partially deleted U3 region of the 3'LTR replaced by a heterologous promoter and a DNA sequence followed by R-U5, see claims 1, 4, 9, 10, 13, 15-17, 19-24 and Figures 4 and 10. Gilboa also teach a host cell complementing elements that are missing in the recombinant vector deficient in viral replication, see column 2, lines 18-30.

One of ordinary skill in the art at the time the invention was made would have been motivated to replace at least a portion of the 3' LTR U3 region with a heterologous promoter and DNA sequence, taught by Gilboa, into the MMTV of Gunzburg et al. to generate self-inactivating vectors. The proviral DNA from these vectors are transcriptionally inactive, which results in the expression of the heterologous insert. One of ordinary skill in the art would also have been motivated to delete at least a portion of the 3' LTR U3 region within the MMTV of Gunzburg et al. to disable activation of cellular oncogenes. See column 5, lines 5-14 of Gilboa. One of ordinary skill in the art at the time the invention was made would have had a reasonable

expectation of producing an MMTV expressing Sag and 3' LTR U3 region comprising a heterologous promoter and DNA sequence because Gunzburg et al. specifically identify the nucleotides and splice sites required for Sag expression and Gilboa teach that self-inactivating vectors are generated by deleting or replacing any portion of the 3' LTR U3 region. Therefore, the segments required for expression of Sag, taught by Gunzburg et al., and the mutations within the 3' LTR U3 region, taught by Gilboa do not overlap. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley